COPY

IDAHO DEPARTMENT OF
HEALTH & WELFARE

C.L. "BUTCH" OTTER – Governor
RICHARD ARMSTRONG – Director

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CERTIFIED MAIL: 7007 0710 0002 7979 0574

June 30, 2009

Jeff Sayer
Mountain View Hospital
2325 Coronado Street
Idaho Falls, ID 83404-1389

RE: Mountain View Hospital, provider #130065

Dear Mr. Sayer:

Based on the complaint survey completed at Mountain View Hospital on June 16, 2009 by our staff, we have determined that Mountain View Hospital is out of compliance with the Medicare Hospital Conditions of Participation on Governing Body (42 CFR 482.12) and Quality Assessment and Performance Improvement (QAPI) (42 CFR 482.21). To participate as a provider of services in the Medicare Program, a hospital must meet all of the Conditions of Participation established by the Secretary of Health and Human Services.

The deficiencies which caused this condition to be unmet substantially limit the capacity of Mountain View Hospital to furnish services of an adequate level or quality. The deficiencies are described on the enclosed Statement of Deficiencies/Plan of Correction (CMS-2567). A similar form indicates State Licensure deficiencies.

You have an opportunity to make corrections of those deficiencies which led to the finding of non-compliance with the Condition of Participation referenced above by submitting a written Credible Allegation of Compliance. Such corrections must be achieved and compliance verified, by this office, before **July 31, 2009. To allow time for a revisit to verify corrections prior to that date, your Credible Allegation must be received in this office no later than July 23, 2009.**

The following is an explanation of a credible allegation:

Credible allegation of compliance. A credible allegation is a statement or documentation:

- Made by a provider/supplier with a history of having maintained a commitment to compliance and taking corrective actions if required.
- That is realistic in terms of the possibility of the corrective actions being accomplished between the exit conference and the date of the allegation, and
- That indicates resolution of the problems.

In order to resolve the deficiencies the facility must submit a letter of credible allegation to the Department, which contains a sufficient amount of information to indicate that a revisit to the facility will find the problem corrected.

As mentioned above, the letter of credible allegation must indicate that the problems have been corrected as of the date the letter is signed. Hence, a plan of correction indicating that the correction(s) will be made in the future would not be acceptable. Please keep in mind that once the Department receives the letter of credible allegation, an unannounced visit could be made at the facility at any time.

Failure to correct the deficiencies and achieve compliance will result in our recommending that CMS terminate your approval to participate in the Medicare Program. If you fail to notify us, we will assume you have not corrected.

We urge you to begin correction immediately.

If you have any questions regarding this letter or the enclosed reports, please contact me at (208)334-6626.

Sincerely,

SYLVIA CRESWELL
Co-Supervisor
Non-Long Term Care

SC/mlw

ec: Kate Mitchell, CMS Region X Office

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	130065	A. BUILDING _____ B. WING _____	C 06/16/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MOUNTAIN VIEW HOSPITAL	2325 CORONADO STREET IDAHO FALLS, ID 83404

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 000	INITIAL COMMENTS The following deficiencies were cited during the complaint survey of your hospital. Surveyors conducting the recertification were: Patrick Hendrickson, RN, HFS, Team Leader Aimee Hastriter, RN, HFS Teresa Hamblin, RN, MS, HFS Acronyms used in this report include: CFO - Chief Financial Officer CPR - Cardiopulmonary Resuscitation CO - Compliance Officer CO2 - Carbon Dioxide CQI - Continuous Quality Improvement ETT - Endotracheal Tube H&P - History and Physical L&D - Labor and Delivery NICU - Neonatal Intensive Care Unit NNP- Neonatal Nurse Practitioner O2 - Oxygen OR - Operating Room RN - Registered Nurse	A 000		
A 043	482.12 GOVERNING BODY The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body. This CONDITION is not met as evidenced by: Based on interviews and review of Quality Assurance and Performance Improvement documents, Medical Staff Bylaws, Medical Executive Committee meeting minutes, Board of	A 043	MVH Response to CMS Audit Attachment #1 See	7/23/09

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Compliance Offr 7-29-09

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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A 043	Continued From page 1 Managers meeting minutes, patient records and hospital policies, it was determined the governing body failed to ensure that the medical staff were accountable to the governing body for the quality of care provided to patients. Further, it was determined the governing body failed to ensure the hospital maintained an effective quality assessment and performance improvement program. This resulted in a missed opportunity for systematic reviews to improve patient care and outcomes. 1. Refer to A049 as it relates to medical staff accountability and the failure of the governing body to develop and implement a written process for the overall review of the quality of physicians' practices, such as a peer review process. 2. Refer to A263 Condition of Participation as it relates to the failure of the hospital to ensure the Quality Assurance and Performance Improvement program analyzed all quality indicators in order to assess processes of patient care and the hospital's code blue responses. The cumulative effective of these negative facility practices seriously impeded the ability of the hospital to provide safe and effective care.	A 043		
A 049	482.12(a)(5) MEDICAL STAFF - ACCOUNTABILITY [The governing body must] ensure that the medical staff is accountable to the governing body for the quality of care provided to patients. This STANDARD is not met as evidenced by: Based on interviews and review of Quality Assurance and Performance Improvement documents, Medical Staff Bylaws, Medical	A 049	See MVH Attachment #1 CMS Response	7/23/09

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A 049	Continued From page 2 Executive Committee meeting minutes, patient records and hospital policies, it was determined the governing body failed to ensure a medical review process was developed and implemented and that medical staff were accountable to the governing body for the quality of care provided to patients. This resulted in 2 of 2 patients (#1 and #4), who had complications at the hospital, not having their cases reviewed by one or more objective, qualified practitioner(s) for the quality of care delivered to the patients. This failure resulted in the inability of the governing body to direct hospital staff in the identification and review process of physicians' patient care practices. The findings include: Patient #1 was admitted to the hospital on 12/11/08 to deliver her first child. There were complications during the delivery that lead the death of infant, Patient #4. The cases were not reviewed for the quality of care provided by the physicians. Patient #1 was a 30 year-old female who presented to the hospital L&D department at 6:14 AM on 12/11/08, according to the L&D flow sheet from that date. According to the L&D flow sheet, on 12/11/08 at 5:39 PM, the nurse reported to Patient #1's obstetrician, who was in the room at this time, that caput was noted on the vaginal exam. Medline Plus, an online medical encyclopedia, states caput succedaneum is a swelling of the scalp in a newborn from the pressure of the uterus or vaginal wall during a head-first delivery. Typically no treatment is necessary and it usually resolves in a few days. The physician's H&P, dated 12/11/08 10:08 PM, noted there was a	A 049		

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A 049	Continued From page 3 significant amount of caput but the baby had dropped further down into the vaginal canal. The L&D flow sheet documented, on 12/11/08 at 5:41 PM, the baby's baseline heart rate was 180 beats per minute and further documented this was tachycardia. Medline Plus, an online encyclopedia, documented the normal range for fetal heart rate is 120-160 beats per minute. At 5:45 PM, the physician recommended the mother continue pushing for 30 minutes. At 6:01 PM, the L&D flow sheet documented the baby's baseline heart rate was 170 beats per minute. At 6:05 PM, the physician returned to the room to evaluate the mother. The physician H&P, dated 12/11/08 at 10:08 PM, noted that at the time of this examination the baby had made little change in position in the vaginal canal. At 6:15 PM, the L&D flow sheet documented the baby's baseline heart rate was 175 beats per minute. The L&D flow sheet documented the physician spoke with Patient #1, and it was decided to attempt assisting the delivery using vacuum extraction. According to the flow sheet, the vacuum pressure was applied and released two times beginning at 6:21 PM. The L&D flow sheet documented at 6:25 PM, the physician decided to proceed with an urgent cesarean section surgery. The L&D flow sheet documented continued fetal tachycardia with the baby's baseline heart rate at 185 beats per minute at 6:30 PM. The heart rate increased to 195 beats per minute at 6:33 PM. The L&D flow sheet noted the patient arrived in the OR at 6:35 PM, and further documented the OR clock was ahead of the clock used to that point of documentation. The arrival, according to the OR clock was 6:40 PM. The H&P, dated 12/11/08 at 10:08 PM, noted the incision was	A 049		

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A 049	Continued From page 4 made at 6:48 PM. The physician's OR report, dated 12/11/08 at 10:08 PM, noted there were "challenges" in delivering the fetal head. The decision was made to pull the baby out by the feet. The feet and arms delivered without complication, the head delivered after extending the abdominal incision. The obstetrician's H&P, dated 12/11/08 at 10:08 PM, noted the baby was delivered at 6:53 PM. The L&D nurse who was present for the delivery was interviewed on 6/04/09, from 9:50 AM to 10:09 AM. She explained that after the obstetrician attempted vacuum extraction with two "gentle tugs," he ordered a cesarean section to deliver the baby. She recalled that after the initial incision was made, it appeared that the baby was lodged in the pelvis. She stated that she offered twice to provide counter-pressure (pushing upward into the vaginal canal) to assist with the delivery of the head. She reported that both times the physician declined assistance. No documentation was found related to this conversation. The nurse also verified that the physician had to lengthen the abdominal incision to dislodge the infant's head. The infant's (Patient #4's) admissions summary sheet stated he was born on 12/11/08 at 6:53 PM, and then transferred to a secondary hospital at 8:11 PM, 1 hour and 18 minutes later. A respiratory therapist note, documented on 12/11/08 at 6:45 PM, stated she was in the operating room for the urgent cesarean section because it was a "difficult delivery." She further documented that when Patient #4 was born, he grunted once and was pale with no respirations. His heart rate was 73 beats per minute at that	A 049		

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A 049	Continued From page 5 time. She documented that staff attempted to intubate the infant 3 times and then the NNP tried to intubate twice without success. After the NNP's unsuccessful attempts to intubate, the pediatrician tried to intubate 3 times and was successful on the third attempt. Nursing notes documented the following: 12/11/08 at 6:53 PM, Patient #4 was delivered by the obstetrician by both of his feet, with a difficult delivery of the head. His head color was pale and he had no muscle tone and a heart rate of 80 beats per minute. Intravenous access was attempted multiple times. 12/11/08 at 6:57 PM, the heart rate was documented at 80 beats per minute and the infant's color was pale. Patient #4 was noted to be gasping. The respiratory therapist attempted to intubate but lung sounds were not heard so they continued to bag mask the infant. NursingTimes.net, an online nursing journal, described the method to bag mask a patient. The bag mask would deliver oxygen to a patient utilizing a face mask over the mouth and nose of the patient and squeezing the bag attached to this mask to force air into the lungs, much like inhalation. An oxygen source would generally be connected into the system to deliver a higher concentration of oxygen. 12/11/08 at 7:03 PM, Patient #4 was floppy and pale. The respiratory therapist attempted to intubate and was unable to. Oxygen was being delivered to him using a bag mask. His heart rate was 80 beats per minute, and according to the medication distribution sheet, epinephrine was given at this time.	A 049		

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A 049	Continued From page 6 12/11/08 at 7:05 PM, the respiratory therapist again attempted to intubate, but the nurse was unable to hear air exchange or a heart beat. Oxygen continued to be delivered to Patient #4 by bag mask. 12/11/08 at 7:08 PM, Patient #4 was intubated by the nurse anesthetist. The nurse heard air exchange at that time and noted a chest rise, but the infant had no heart rate and chest compressions were started. 12/11/08 at 7:13 PM, the NNP arrived at the infant's bedside and assessed Patient #4. The NNP "visualized" the ETT placement, the infant's chest movement was lost, and she attempted to reintubate him. 12/11/08 at 7:19 PM, the post-surgical charge nurse called for a transport team to transfer the baby to a secondary hospital. 12/11/08 at 7:36 PM, Patient #4's heart rate was 100 beats per minute but no spontaneous respirations were noted. 12/11/08 at 7:38 PM, the NNP infused sodium bicarbonate 1.2 mEq. The remainder of 6 mEq was to be infused over the next 5 minutes. However, the infusion was stopped after 1 minute. The NNP's H&P, dictated on 12/12/08 at 3:04 AM, stated sodium bicarbonate was given, a total of 6 mEq, and then a sodium bicarbonate drip was started. The infant's Medication Distribution Record stated 6 mEq sodium bicarbonate was given over 10 minutes, but was stopped after 1 minute. No further documentation was found to explain the discrepancies.	A 049		

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A 049	Continued From page 7 The Nursing 2008 Drug Handbook stated sodium bicarbonate is used in cardiac arrest patients. The American Academy of Pediatrics, Neonatal Resuscitation Program, Worksheet for Proposed Evidence-Based Guideline Recommendations, 2005 stated "Sodium bicarbonate is discouraged during brief CPR but may be useful during prolonged arrests after adequate ventilation is established and there is no response to other therapies" in the "absence of adequate ventilation, sodium bicarbonate administration can exacerbate intracellular hypercarbia and worsen intracellular acidosis." 12/11/08 at 7:52 PM, the transport team arrived to transport Patient #4 to the secondary hospital. An H&P, dictated on 12/12/08 at 3:04 AM, by the NNP was reviewed. She dictated that she was called at 6:59 PM, to come emergently to the hospital to help resuscitate an infant that had a heart rate of 80 beats per minute. She documented she was told the obstetrician had performed an emergency cesarean section because the infant was "stuck" and failed to progress. She arrived at the hospital at 7:08 PM, 15 minutes after Patient #4's birth. The NNP stated in the H&P that when she arrived, the baby was being ventilated via an ETT. She described the baby as being extremely pale. She noted there were no cardiac or respiratory monitors on the baby. She documented a pulse oximeter was not in place, nor had anyone obtained intravenous access at that time. The NNP stated in her H&P that chest compressions were being done by an RN, and respiratory therapy was managing the infant's airway. She documented she listened for a heart beat, and found the baby had none.	A 049		

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A 049	Continued From page 8 The H&P further documented the NNP asked for an end-tidal CO2 monitor to see if the infant was intubated properly. This was the first documentation of this process being completed; it was 20 minutes after birth. The American Academy of Pediatrics, Neonatal Resuscitation Program, Worksheet for Proposed Evidence-Based Guideline Recommendations, 2003, stated CO2 detectors should be recommended as standard of care for secondary confirmation of endotracheal intubation in resuscitation of neonates. The Neonatal Resuscitation Program dated 2006, stated this diction was an effective way for secondary confirmation of correct intubation. The NNP's H&P stated the CO2 check was negative. She reintubated Patient #4 and the CO2 monitor turned slightly positive. According to the nursing notes, this was around 7:13 PM, 20 minutes after birth. She documented that upon assessment she could hear breath sounds and saw chest movement, but the infant's heart rate and color did not improve. She also documented that she had obtained intravenous access through a 5-French umbilical venous catheter and gave fluids and medications at 7:18 PM, according to Patient #4's medication distribution sheet. The NNP documented, in the H&P dictated 12/12/08 at 4:03 AM, a pediatrician arrived at Patient #4's bedside 7 minutes after her. This was 22 minutes after birth. She documented the pediatrician visually checked to see if the ETT was placed correctly. It was determined that it was in place, but may have been plugged by mucous. She stated in the H&P that the pediatrician removed the ETT and placed another one. This was documented by nursing, in the	A 049		

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A 049	Continued From page 9 nursing notes, at 7:24 PM. The NNP's H&P documented a chest x-ray was taken. A nursing note dated 12/11/08, stated that this was done at 7:28 PM. The H&P also noted the x-ray results showed the ETT was too far into the trachea. It was then pulled back and re-secured. She stated a pulse oximetry check showed the baby's oxygen saturation was 77%. Mosby's Diagnostic and Laboratory Test Reference 1997, documented possible critical values of O2 saturations as 75% or lower. The NNP documented that Patient #4's color and perfusion began to improve, with color changing to a normal pink, starting from head to toe. The infant's heart rate was greater than 100 at 7:31 PM, 38 minutes after birth. She noted the infant's head was "very boggy," suspicious of a subgaleal bleed. Emedicine, an online medical reference found at emedicin.medscape.com, stated a subgaleal hematoma is a bleed in the potential space between the skull and the scalp. A pediatrician's progress note, dictated on 12/11/08 at 10:39 PM, stated he was called at approximately 7:13 PM, 20 minutes after birth, and arrived at the infant's bedside at approximately 7:20 PM, 27 minutes after birth. He documented Patient #4 had no heart rate when he arrived. He stated he could hear air movement through both lungs and verified that the ETT was placed correctly. He had concerns that the CO2 detector did not show evidence of CO2 and the tube was removed and the infant reintubated. The pediatrician's progress note stated medications and fluids were given and at approximately 36 minutes of life, the infant responded with a heart rate and the CO2 detector became positive. He documented the baby had	A 049		

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A 049	Continued From page 10 agonal respiratory efforts. According to the website, firstaid.about.com, an online medical reference, agonal respirations are slow, gasping breaths not adequate enough to provide oxygen to the body and should be considered as not breathing at all. The pediatrician documented on a different physician's progress note, dated 12/11/08 that was not timed. He stated that resuscitation efforts were discontinued at the secondary hospital when it was clear that the infant was not viable. Patient #4 was then transported back to Mountain View Hospital on 12/11/08 at 9:25 PM, as documented in the nursing notes. Soon after, ventilation was discontinued and the pediatrician declared the infant's time of death as 10:46 PM. The secondary hospital's neonatologist's H&P, dated 12/12/08 at 7:41 AM, stated he was told there was a failure of progression of the fetus with the head stuck in the birth canal. An emergency cesarean section was done to get the child out secondary to variable decelerations. It was documented that immediately after delivery Patient #4 was noted to have no respiratory effort. He was told that intubation was performed by hospital staff at Mountain View Hospital. He documented that no CO2 detection was placed on the ETT to confirm proper placement. He was informed the patient's heart rate dropped and oxygen saturations did not improve with intubation. He stated by report the baby did not have an adequate heart rate at 30 minutes of life, and the baby was noted to be limp, pale, and cyanotic with diminished pulses. The neonatologist noted that his exam revealed a pale, apneic, infant with agonal respirations. The infant had decorticate posturing with hypertonicity	A 049		

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A 049	Continued From page 11 of the upper and lower extremities. Merriam Webster online medical dictionary defined a decorticate posture as "abnormal posturing that involved rigidity, flexion of the arms, clenched fists, and extension of the legs. The arms would be bent inward towards the body with the wrists and fingers bent and held on the chest...It was a sign of severe brain damage and requires immediate medical attention". Further, he documented the exam revealed a subgaleal hemorrhage. Patient #4's anterior frontal head was soft and flat. His pupils were equal and minimally reactive to light. The decision was made, after discussion with the infant's father, to end resuscitation efforts secondary to prolonged asphyxia . The online Merriam Webster Dictionary (2009), defined asphyxia as a "lack of oxygen or excess of carbon dioxide in the body that would result in unconsciousness and often death and was usually caused by interruption of breathing or inadequate oxygen supply." The infant was subsequently transported back to Mountain view Hospital to allow the mother to hold the baby where the pediatrician later pronounced the infant's death. The secondary hospital's neonatologist's H&P, dated 12/12/08 at 7:41 AM, stated his impressions included, but were not limited to, perinatal asphyxia likely immediately at delivery or shortly after, severe hypoxic ischemic encephalopathy, and severe mixed acidosis both metabolic and respiratory. The secondary hospital's neonatologist, involved in this case was interviewed on 6/04/09 at 11:15 AM. He reported that he was notified of this incident and was part of the transport team as the infant was taken to and from the involved	A 049		

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A 049	Continued From page 12 hospitals. He recalled the infant had obvious severe brain damage on physical exam, and after 15-20 minutes of continued resuscitation efforts at the secondary hospital, they discontinued aggressive treatments. The infant was left on life support measures, and the family was informed of the infant status and their options for further treatment or discontinuation thereof. The neonatologist expressed frustration at not being notified sooner, even on a consultative basis. He stated he was in his office, which was near the primary hospital, at the time of delivery and would have made himself available in any capacity that would have been helpful to save this infant. He stated that, given the status of the infant immediately after delivery, the injuries sustained most likely came from the delivery process itself. The neonatologist stated that the primary hospital had requested his partner to be involved in the review of this case. He stated he was "almost sure" the results of the autopsy were discussed as well as recommended possible policy changes to implement. The infant's autopsy report, dated 1/04/09 at 9:45 PM, documented the infant suffered a blunt force trauma to the head. The infant had a contusion/abrasion on the right upper scalp measuring up to 2 inches. The report documented the infant had a subscapular red/blue hematoma overlying below a skull fracture of the right parietal bone. The report noted the infant had a bilateral subdural hematoma that involved the convexities at the base of the infant's brain. The report further documented there was diffuse subarachnoid hemorrhaging of the parietal and occipital lobes of the brain. The report documented there was noted blunt force trauma to the right lower leg	A 049		

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A 049	Continued From page 13 with a blue/black contusion over the length below the knee to the ankle that was roughly circumferential. The infant's Birth Certificate Information, physician's worksheet for Baby Data Sheet, dated 2/04/09 that was not timed, but was filled out by the NNP from the primary hospital, documented the infant sustained a "Significant birth injury (skeletal fracture, peripheral nerve injury, and/or soft tissue/solid organ hemorrhage which requires intervention)." The Occurrence Report Review was completed by the hospital's CO on 1/06/09, and amended 6/04/09 with the addition of a telephone interview of the second nursery RN who assisted with the infant's resuscitation. It documented one of the questions addressed was whether to proceed with a peer review. The chief of medicine (who was an orthopedic surgeon), deferred these decisions to the chairman of the board, who was a member of the American College of Obstetricians and Gynecologists. The chairman of the board was the surgeon called in to assist with surgical repair after the cesarean section. The CO documented the results of the 1/06/09 investigation were then discussed with the hospital's administration. In an interview on 6/03/09 at 11:05 AM, the CO stated that a peer review would only be generated as a result of a complaint from a physician or another facility. During the interview on 6/04/09 at 2:17 PM, the CO stated that after his investigation was complete, the chairman of the Board of Managers took this information to the Medical Executive Committee. The Medical Executive Committee meeting minutes were reviewed. Meeting	A 049		

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A 049	Continued From page 14 minutes, dated 03/11/09, stated Patient #4's file was reviewed. It stated no peer review was needed and the hospital would "trend" the obstetrician for other cases. He stated that a neonatologist did not do a peer review of this case. The CO was asked for the peer review policy on 6/03/09. He provided a copy of the MEDICAL STAFF BYLAWS, sections 4.6.3 through 7.2. The documents did not state when, how and who would do a medical review nor did they have any language about a medical review process. During the interview on 6/04/09 at 2:17 PM, the CO stated the hospital did not have a policy that would have guided the hospital staff in the decision of obtaining an objective medical "peer review" of Patient #1's and Patient #4's cases. The CFO of the hospital was interviewed on 6/04/09 from 2:03 PM to 2:15 PM. He stated peer review of the care provided to Patient #1 and Patient #4 was not completed because it was felt the physicians' involved in the case did nothing wrong. On 6/10/09 at 9:00 AM, the CO stated he had just developed a policy on peer review and it would be brought to the Medical Executive Committee meeting for approval. The governing body failed to ensure policies and procedures were developed and implemented to thoroughly and effectively assess the quality of care provided by the hospital's medical staff.	A 049		
A 263	482.21 QAPI The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance	A 263		

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A 263	Continued From page 15 improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS. This CONDITION is not met as evidenced by: Based on interviews and review of Quality Assurance and Performance Improvement documents, Medical Staff Bylaws, Medical Executive Committee meeting minutes, Board of Managers meeting minutes, patient records, and hospital policies, it was determined the hospital failed to maintain an effective Quality Assessment and Performance Improvement program. This resulted in a missed opportunity for systematic reviews to improve patient care and outcomes. The findings include: 1. Refer to A267 as it relates to the failure of the hospital to ensure its Quality Assurance and Performance Improvement program analyzed all quality indicators in order to assess processes of patient care and hospital services.	A 263	See Attachment #1 MVH Response CMS Audit Survey	7/23/09
A 267	482.21(a)(2) QAPI QUALITY INDICATORS The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital services and operations.	A 267	See Attachment #1 MVH Response CMS Audit Survey	7/23/09

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A 267	Continued From page 16 This STANDARD is not met as evidenced by: Based on interviews and review of Quality Assurance and Performance Improvement documents, Medical Staff Bylaws, Medical Executive Committee meeting minutes, Board of Managers meeting minutes, patient records and hospital policies, it was determined the hospital failed to ensure the Quality Assurance Program analyzed all quality indicators and patient adverse events in order to assess processes of care and hospital services for 2 of 17 patients (#1 and #4) whose records were reviewed. This resulted in the inability of the hospital to develop and implement changes to improve patient care. The findings include: The hospital's Quality Assurance Program failed to fully review Patient #1's and Patient #4's care. The Quality Assurance Program failed to fully investigate the cares provided; such as the physician declining counter pressure and CPR provided to Patient #4. Further, the Quality Assurance Program failed ensure it had policies that were adequate and/or followed, in relation to on-call physician's response time and transport time. The hospital's Quality Assurance Program failed to follow the hospital's own transfer policy and failed to have the Performance Improvement committee review the case for quality. The hospital's Quality Assurance Program failed to identify that staff had not followed the hospital's Oxygen policy, and failed to identify that a CO2 detector was not used in the initial intubation attempts on Patient #4. Further, the hospital's Quality Assurance Program failed to identify that	A 267	See Attachment #1 MVA Response to CMS Audit survey	7/23/09

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A 267	Continued From page 17 staff had not completed a RECORD OF CHILD CPR form. This resulted in the lack of valuable and accurate information had the Performance Improvement committee reviewed the code response for quality. The hospital's Quality Assurance Program failed to follow the hospital's Sentinel Event Policy. The hospital's Quality Assurance Program failed to perform a root cause analysis of the event. If the Sentinel Event Policy had been initiated, an analysis would have been presented to the CQI Committee and the Board of Managers, and the departments would have conducted a Failure Mode and Effects Analysis annually. Lastly, the hospital's Quality Assurance Program failed to interview all staff involved with Patient #1 and Patient #4's case and also failed to ensure the hospital had developed a policy for the overall review of physician practices the medical care provided. The findings include: 1. Patient #1 was a 30 year-old female who presented to the hospital's L&D department at 6:14 AM on 12/11/08, according to the L&D flow sheet from that date. She was assessed and monitors were applied to record the timing, length, and strength of the uterine contractions. At 7:26 AM, her obstetrician was notified and he gave orders to admit the patient. The L&D flow sheet noted the patient had epidural anesthesia at 8:22 AM and at 12:39 PM, Pitocin was given to augment uterine contractions. The L&D flow sheet documented that, at 3:17 PM on 12/11/08, the obstetrician was notified Patient #1 was completely dilated, but the baby was still high in the vaginal canal. The physician	A 267		

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A 267	Continued From page 18 recommended that she continue with labor for an hour and then begin actively pushing. Pushing was initiated at 4:16 PM. According to the L&D flow sheet, at 5:39 PM on 12/11/08, the nurse reported to Patient #1's obstetrician, who was in the room at this time, that caput was noted on the vaginal exam. Medline Plus, an online medical encyclopedia, states caput succedaneum is a swelling of the scalp in a newborn from the pressure of the uterus or vaginal wall during a head-first delivery. Typically no treatment is necessary and it usually resolves in a few days. The physician's H&P, dated 12/11/08 10:08 PM, noted there was a significant amount of caput but the baby had dropped further down into the vaginal canal. The L&D flow sheet documented, on 12/11/08 at 5:41 PM, the baby's baseline heart rate was 180 beats per minute and further documented that this was tachycardia. Medline Plus, an online encyclopedia, documented the normal range for fetal heart rate is 120-160 beats per minute. At 5:45 PM, the physician recommended the mother continue pushing for 30 minutes. At 6:01 PM, the L&D flow sheet documented the baby's baseline heart rate was 170 beats per minute. At 6:05 PM the obstetrician returned to the room to evaluate the mother. The physician H& P, dated 12/11/08 at 10:08 PM, noted that at the time of this examination the baby had made little change in his position in the vaginal canal. At 6:15 PM, the L&D flow sheet documented the baby's baseline heart rate was 175 beats per minute. The physician spoke with Patient #1 and it was decided to attempt assisting the delivery using vacuum extraction. According to the flow sheet, the vacuum pressure was applied and	A 267		

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A 267	Continued From page 19 released two times beginning at 6:21 PM. At 6:25 PM, the obstetrician decided to proceed with an urgent cesarean section surgery. The L&D flow sheet documented continued fetal tachycardia with the baby's baseline heart rate at 185 beats per minute at 6:30 PM. The heart rate increased to 195 beats per minute at 6:33 PM. The L&D flow sheet noted the patient arrived in the OR at 6:35 PM, and further documented the OR clock was ahead of the clock used to that point of documentation. The arrival, according to the OR clock was 6:40 PM. The obstetrician's H&P, dated 12/11/08 at 10:08 PM, noted the incision was made at 6:48 PM. The obstetrician's OR report, dated 12/11/08 at 10:08 PM, noted there were "challenges" in delivering the fetal head. The decision was made to pull the baby out by the feet. The feet and arms delivered without complication, the head delivered after extending the abdominal incision. The obstetrician's H&P, dated 12/11/08 at 10:08 PM, noted the baby was delivered at 6:53 PM. Once the infant had been delivered, the obstetrician requested another surgeon be called in to assist him in completing the surgery on Patient #1. According to the L&D flow sheet, this occurred at 6:55 PM. The L&D flow sheet documented a pediatrician was called at 6:56 PM, to come in. It further documented that at 6:58 PM, the NNP was called to assist. At 7:01 PM, the pediatrician returned the phone call stating that he was not on call, the NNP was on call for his pediatric group. The L&D flow sheet documented at 7:02 PM, the correct physician, a member of a different pediatric group and the pre-selected pediatrician for the baby,	A 267		

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A 267	Continued From page 20 was called to come in. According to the L&D flow sheet, surgery was completed on the mother at 8:12 PM, and she was removed from the OR at 8:32 PM. An interview was conducted with the obstetrician on 6/04/09 at 8:54 AM. He reviewed the delivery and verified that the cesarean section was done for arrested descent of the infant. He stated the feet were brought out through the incision and he thought the uterus clamped down around the baby's head making it difficult to completely deliver the infant. The physician also verified the delivery of the infant took place about five minutes after the incision. He stated a second surgeon was then called in to assist with repair of the uterus. The L&D nurse who was present for the delivery was interviewed on 6/04/09, from 9:50 AM to 10:09 AM. She explained that after the obstetrician attempted vacuum extraction with two "gentle tugs," he ordered a cesarean section to deliver the baby. She recalled that after the initial incision was made, it appeared that the baby was lodged in the pelvis. She stated that she offered twice to provide counter-pressure (pushing upward into the vaginal canal) to assist with the delivery of the head. She reported that both times the physician declined assistance. No documentation was found related to this conversation. The nurse also verified that the physician had to lengthen the abdominal incision to dislodge the infant's head. The investigation report, titled the Occurrence Report Review was completed by the hospital's CO on 1/06/09. It was amended 6/04/09 with the	A 267		

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A 267	Continued From page 21 addition of a telephone interview of the second nursery RN who assisted with the infant's resuscitation. One question asked was if there was excessive force used on the baby's head in order to deliver the infant. The Occurrence Report Review documented that while force was applied, there was insufficient evidence to demonstrate that the force was excessive. The chairman of the board (who was the surgeon called in to assist with surgical repair after the cesarean section), determined that this event did not warrant peer review and the CO reviewed the physician's file and found no other cases of the use of excessive force. The Occurrence Report Review documented the use of force used in deliveries would continue to be monitored. The Quality Assurance Program failed to fully investigate the care provided. The Quality Assurance Program failed to identify and review the physician declining counter pressure during the delivery and whether policies were adequately followed in relation to on-call physician response time and the transport time related to Patient #4. 2. Patient #4 was born on 12/11/08 at 6:53 PM, and was transferred to a secondary hospital at 8:11 PM, 1 hour and 18 minutes later. This was documented in the hospital's admission summary sheet for the infant. The following documentation was obtained from the infant's medical records at Mountain View Hospital. A respiratory therapy note, dated 12/11/08 at 6:45 PM, stated the therapist was called to the operating room for an urgent cesarean section because it was a "difficult delivery." She	A 267		

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A 267	Continued From page 22 documented that when Patient #4 was born, he grunted once and was pale with no respirations. His heart rate was 73 beats per minute at that time. She documented that staff attempted to intubate the infant 3 times and then the NNP tried to intubate twice without success. After the NNP's unsuccessful attempts to intubate, the pediatrician tried to intubate 3 times and was successful on the third attempt. The respiratory therapist was interviewed on 6/03/09 from 3:49 PM to 3:56 PM. She stated after the delivery there were difficulties with establishing an airway for Patient #4. She said that she had the ETT in place. She stated she heard breath sounds and witnessed exhalation vapor in the tube, and that both signs would be indicators of an appropriate intubation. She stated that in her 23 years of experience, one can't always rely on visualizing the vocal cords to determine if the airway has been established. Later in the interview, she stated that she had visualized the vocal cords. She felt sure the ETT was in place, but because of low perfusion, the CO2 indicator didn't change. The respiratory therapist stated that everyone questioned whether the ETT was in. She also stated that initially Patient #4 had no heart beat. This was inconsistent with documentation found in Patient #4's record. She further stated she was not a part of any debriefing session conducted regarding the incident, but the CO did speak with her. She stated no changes in policy or procedures had been made since the incident that she was aware of. Nursing notes documented the following: 12/11/08 at 6:53 PM, Patient #4 was delivered by	A 267		

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A 267	Continued From page 23 the obstetrician by both of his feet with a difficult delivery of the head. His head color was pale and he had no muscle tone and a heart rate of 80 beats per minute. Intravenous access was attempted multiple times. The Occurrence Report Review, dated 1/04/09, did not include investigation or other information describing the reasons why intravenous access was not obtained by nursing staff. 12/11/08 at 6:57 PM, Patient #3's heart rate was documented at 80 beats per minute and his color was pale. He was noted to be gasping. The respiratory therapist attempted to intubate but lung sounds were not heard so they continued to bag mask the infant. NursingTimes.net, an online nursing journal, described the method to bag mask a patient. The bag mask delivers oxygen to a patient utilizing a face mask over the mouth and nose of the patient and squeezing the bag attached to the mask to force air into the lungs, much like inhalation. An oxygen source would generally be connected into the system to deliver a higher concentration of oxygen. 12/11/08 at 7:03 PM, Patient #4 was floppy and pale. The respiratory therapist attempted to intubate and was unable to. Oxygen was being delivered to the baby using a bag mask. His heart rate was 80 beats per minute, and according to the medication distribution sheet, epinephrine was given at this time. 12/11/08 at 7:05 PM, the respiratory therapist again attempted to intubate, but the nurse was unable to hear air exchange or a heart beat. Oxygen continued to be delivered to Patient #4 by bag mask.	A 267		

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A 267	Continued From page 24 12/11/08 at 7:08 PM, Patient #4 was intubated by the nurse anesthetist. The nurse heard air exchange at that time and noted a chest rise, but the infant had no heart rate and chest compressions were started. 12/11/08 at 7:13 PM, the NNP arrived at the infant's bedside and assessed Patient #4. The NNP "visualized" the ETT placement, the infant's chest movement was lost and she attempted to reintubated him. 12/11/08 at 7:19 PM, the post-surgical charge nurse called for a transport team to transfer the baby to a secondary hospital. 12/11/08 at 7:36 PM, Patient #4's heart rate was 100 beats per minute but no spontaneous respirations were noted. 12/11/08 at 7:52 PM, the transport team arrived to transport Patient #4 to the secondary hospital. The Occurrence Report Review, dated 1/04/09, did not evaluate the response time of the transport team's 23 minute response to identify ways to facilitate improved response times. The hospital's Transfer of Patients from (Hospital's Name) Policy #410 dated 9/04/06, stated the hospital was to review 100% of all records of patients transferred out of the hospital to determine that the appropriate standard of care had been met. The policy did not identify whose responsibility it was to complete this review. The hospital's 2008 Patient Transfer Log documented the hospital had transferred out 20 infants. The hospital's 2009 Patient Transfer Log documented	A 267		

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A 267	Continued From page 25 the hospital had transferred out 3 infants. The hospital's Quality Perinatal 2008 Statistics showed no documentation the transfer records were reviewed. During an interview with the hospital's CO on 6/10/09 at 9:30 AM, he stated that the hospital was "now" going to review the records of patients transferred to another hospital. The hospital failed to follow it's transfer policy. This resulted in the inability of the hospital to assess whether the care provided to Patient #4, prior to his transfer, was consistent with current standards of practice. 3. The RN, with extensive NICU experience primarily responsible for the care of Patient #4, was interviewed on 6/03/09 at 2:36 PM. She was called to the delivery when the physician was applying vacuum suction to the infant to assist with the delivery. She recalled the physician attempted with the vacuum twice and then opted for the cesarean section. She recalled the difficulty in getting Patient #4 out of the mother and stated the head was "stuck." Once the infant was delivered she began the resuscitation and called for a second nursery RN to assist with resuscitation. Soon after initiating resuscitation, the NNP and pediatrician arrived and took control of the emergency. The RN interviewed stated that initially they had a heart rate, but then lost it. She stated the respiratory therapist attempted to intubate twice, but was not able to auscultate breath sounds. The nurse believed it was about 40 minutes after birth before they got a heart rate again. The nurse anesthetist, who was in the room at the time of the delivery and whose primary role was	A 267		

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A 267	Continued From page 26 to care for Patient #1 during the cesarean section, was interviewed on 6/04/09 from 9:20 AM to 9:36 AM. He recalled the delivery and verified that due to the difficulty of the resuscitation he did assist with the intubation of Patient #4. He stated he visualized the vocal cords while intubating, and then assisted with breathing for a moment before needing to turn his attention back to Patient #1. He remembers this being a difficult delivery with challenges in removing the infant from the uterus. The hospital's Newborn Resuscitation Policy #PNNSY .22, dated 12/20/02, stated "If a full resuscitation is done, a RECORD OF CHILD CPR form should be filled out and turned into the CODE BLUE COMMITTEE for review and Performance Improvement." During an interview with the hospital's CO, on 6/10/09 at 9:10 AM, he stated that this policy was not followed. A record of Child CPR was not filled out and the Code Blue Committee did not review the incident. The failure of staff to complete a RECORD OF CHILD CPR form resulted in the lack of valuable and accurate information that could have been used for review of the staffs' intubation and response processes. The hospital's Quality Assurance Program failed to ensure the Performance Improvement Committee reviewed the case for quality. As a result, hospital systems, physician practices, and staff responses related to the code and repeated unsuccessful attempts to intubate Patient #4, were not evaluated to identify potential opportunities for improvement. 4. An H&P, dictated on 12/12/08 at 3:04 AM, by the NNP was reviewed. It stated she was called at 6:59 PM on 12/11/08, to come emergently to	A 267		

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A 267	Continued From page 27 the hospital to help resuscitate an infant that had a heart rate of 80 beats per minute. The NNP documented she was told the obstetrician had performed an emergency cesarean section because the infant was "stuck" and failed to progress. She arrived at the hospital at 7:08 PM, 15 minutes after Patient #4's birth. The NNP stated in the H&P that when she arrived, the baby was being ventilated via an ETT. She described the baby as being extremely pale. She noted there were no cardiac or respiratory monitors on Patient #4. She documented a pulse oximeter was not in place, nor had anyone obtained intravenous access at that time. The hospital's Oxygen Policy #PNNSY.23 dated 12/20/02, stated staff were to "Give infant immediate blowby oxygen for any duskiness or cyanosis" and to "Place on pulse oximetry." Pulse oximetry, according to Merriam Webster online medical dictionary, was the use of a device to measure the level of oxygen in a patient's blood through a sensor attached to the baby's foot or wrist. On 6/16/09 at 4:08 PM, the NNP was interviewed. She confirmed that a pulse oximeter was not in place when she arrived to the bedside of the child. She stated a pulse oximeter was not readily available in the OR and felt one needed to be in the OR. The failure of the hospital's staff to follow this policy resulted in the inability to monitor Patient #4's blood oxygen level during CPR efforts. This was not identified by the hospital's Quality Assurance Program. 5. The NNP stated in her H&P, dated 12/12/08 at 3:04 AM, that chest compressions were being done by an RN and respiratory therapy was	A 267		

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A 267	Continued From page 28 managing the infant's airway. She documented she listened for a heart beat and found the baby had none. The H&P stated the NNP asked for an end-tidal CO2 monitor to see if the infant was intubated properly. This was the first documentation of this process being completed. The American Academy of Pediatrics, Neonatal Resuscitation Program, Worksheet for Proposed Evidence-Based Guideline Recommendations, 2003, stated CO2 detectors should be recommended as standard of care for secondary confirmation of endotracheal intubation in resuscitation of neonates. The Neonatal Resuscitation Program dated 2006, stated this diction was an effective way for secondary confirmation of correct intubation. On 6/16/09 at 4:08 PM, the NNP was interviewed. She stated that staff did have a difficult time intubating Patient #4. She stated that due to the fact that staff had not had a CO2 detector in place, it limited them in evaluating proper intubation. The failure of the hospital's staff to have a CO2 detector on Patient #4's ETT impeded staff's ability to determine if he was properly intubated. This was not identified by the hospital's Quality Assurance Program. 6. The NNP's H&P, dated 12/12/08 at 3:04 AM, stated the CO2 check was negative. She reintubated Patient #4 and the CO2 monitor turned slightly positive. According to the nursing notes, this was around 7:13 PM on 12/11/08, 20 minutes after birth. She documented that upon assessment, she could hear breath sounds and saw chest movement, but Patient #4's heart rate and color did not improve. She also documented	A 267		

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A 267	Continued From page 29 she obtained intravenous access through a 5-French umbilical venous catheter and gave fluids. According to Patient #4s medication distributation sheet this occured on 12/11/08 at 7:18 PM. The NNP's H&P also documented a pediatrician arrived at Patient #4's bedside 7 minutes aftershe did. This was 22 minutes after birth. She documented the pediatrician visually checked to see if the ETT was placed correctly. It was determined that it was in place, but may have been plugged by mucous. She stated in the H&P that the pediatrician removed the ETT and placed another one. This was documented by nursing, in the nursing notes, at 7:24 PM on 12/11/08. The NNP documented in her H&P that a chest x-ray was taken. A nursing note dated 12/11/08, stated this was done at 7:28 PM. The NNP's H&P noted the x-ray results showed the ETT was too far into the trachea. It was then pulled back and re-secured. The NNP's H&P, stated a pulse oximetry check showed the baby's oxygen saturation was 77%. Mosby's Diagnostic and Laboratory Test Reference documented possible critical values of O2 saturations as 75% or lower. The NNP noted that Patient #4's color and perfusion began to improve, with color changing to a normal pink, starting from head to toe. Patient #4's heart rate was greater than 100 at 7:31 PM, 38 minutes after birth. The NNP also documented in the H&P that the infant's head was "very boggy," suspicious of a subgaleal bleed. Emedicine, an online medical reference found at emedicin.medscape.com, documented a subgaleal hematoma was a bleed in the potential space between the skull and the scalp. She also noted the infant's venous blood gas lab results as	A 267		

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A 267	Continued From page 30 follows: PH was 6.54 (Normal 7.33 to 7.49) PCO2 was 89.5 (Normal 27-40) PO2 was 66 (Normal 60-76) HCO3 was 7.7 (Normal 23-30) BE was -30 (Normal -3 to 3) Mosby's Diagnostic and Laboratory Test Reference 1997 indicated the above results would be considered respiratory acidosis (blood with a a low PH). This is commonly caused by prolonged respiratory depression. An investigation report, titled the Occurrence Report Review, completed by the hospital on 1/06/09 and amended 6/04/09, was reviewed. One of the questions addressed in the report was whether Patient #4's airway was managed properly. According to the Occurrence Report Review, it was determined that the airway was extremely difficult to manage but there was no evidence to suggest that staff error contributed to the problem. On 6/16/09 at 4:08 PM, the NNP was interviewed. She stated staff did have a difficult time intubating Patient #4. She stated that due to the fact that staff had not had a pulse oximeter and a CO2 detector in place, it limited them in evaluating proper intubation. The failure of the hospital's staff to follow the Oxygen policy, and have a CO2 detector on Patient #4's ETT, resulted in the staffs' inability to monitor Patient #4's blood oxygen level during the CPR efforts and to fully confirm intubation. Further, the failure of staff to complete a RECORD OF CHILD CPR form resulted in the	A 267		

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A 267	Continued From page 31 lack of valuable and accurate information had the Performance Improvement committee reviewed the code response for quality. The Quality Assurance documents did not identify the above issues. This resulted in the inability of the program to assess the standards of care provided to Patient #4. 7. A pediatrician's progress note, dictated on 12/11/08 at 10:39 PM, stated he was called at approximately 7:13 PM, 20 minutes after birth, and arrived at Patient #4's bedside at approximately 7:20 PM, 27 minutes after birth. He documented Patient #4 had no heart rate when he arrived. He stated he could hear air movement through both lungs and verified that the ETT was placed correctly. He had concerns that the CO2 detector did not show evidence of CO2 and the tube was removed and the infant reintubated. The pediatrician's progress note stated medications and fluids were given and at approximately 36 minutes of life, the infant responded with a heart rate and the CO2 detector became positive. He documented the baby had agonal respiratory efforts. According to the website, firstaid.about.com, an online medical reference, agonal respirations are slow, gasping breaths not adequate enough to provide oxygen to the body and should be considered as not breathing at all. The pediatrician dictated a different physician's progress note, dated 12/11/08 that was not timed. He documented that resuscitation efforts were discontinued at the secondary hospital when it was clear that the infant was not viable. Patient #4 was then transported back to the primary hospital on 12/11/08 at 9:25 PM, as documented in the nursing notes. Soon after, ventilation was	A 267		

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A 267	Continued From page 32 discontinued and the pediatrician declared Patient #4's time of death as 10:46 PM. The hospital's Sentinel Event Policy #RKMG.05 dated 10/08/02, stated a sentinel event was an event that resulted in an unanticipated death or serious physical injury. The policy directed after a sentinel event, the hospital was to perform a root cause analysis of the event, present the analysis to the CQI Committee and the Board of Managers and conduct a Failure Mode and Effects Analysis annually. This Sentinel Event Policy was not followed. The Occurrence Report Review completed by the CO, dated 1/06/09 and amended 6/04/09, documented one of the questions addressed was whether this was considered a sentinel event. The Occurrence Report Review documented that there was no evidence of a process failure that directly contributed to the patient outcome, and that the viability of the infant was determined at the secondary hospital. Based on these two points, it was determined that this incident was not a sentinel event. The Occurrence Report Review stated that once the CO had conducted the interviews and reviewed the charts, he consulted with the chief of medical staff regarding the decision to qualify the incident as a sentinel event. The chief of medicine (who was an orthopedic surgeon), deferred this decision to the chairman of the board, who was a member of the American College of Obstetricians and Gynecologists. This physician was present immediately after the delivery to help complete surgery on the mother. It was determined the case was not a sentinel event.	A 267		

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A 267	Continued From page 33 The CO was interviewed on 6/03/09 beginning at 3:05 PM. He stated that since the infant did not die on the primary hospital's property, and he believed proper processes were involved, the incident did not warrant calling a sentinel event. He stated that one thing did go wrong; the response from the pediatrician who was initially called to come in was inappropriate. During an interview on 6/04/09 beginning at 2:17 PM, the CO again stated that he did not believe this was a sentinel event because there was not a failure in a process that led to the death of the infant. He stated he conducted an investigation as a discovery process, to determine if a system had broken down to cause the incident. Because no process was determined to have failed, a root cause analysis, in his opinion, was not warranted. The vice president of operations was interviewed on 6/04/09 from 1:40 PM to 1:59 PM. He stated that a sentinel event would have been warranted if a process had failed leading to a death. He reiterated that "from his knowledge base" no process had failed and he had no reason to be involved in any investigation. The vice president of operations stated he was not aware that the infant died on the primary hospital's property, and since the hospital did not have access to the autopsy he did not know the cause of death and could not comment on any serious injury that may have occurred. The CFO of the hospital was interviewed on 6/04/09 from 2:03 PM to 2:15 PM. He stated he was familiar with this event but had a level of trust with his staff that included relying on their investigation and handling of the incident. He	A 267		

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A 267	Continued From page 34 was not aware of the details but understood that an investigation was completed and the incident was discussed with the Medical Executive Committee and at a Board level. He stated that none of those groups who had access to the charts and investigation felt it was a sentinel event. He stated that he felt the proper processes had been followed, as specified in the investigation by the CO and surgeon who assisted with the investigation. The CFO further stated he was unaware of any changes in policy or procedure. The hospital failed to follow its Sentinel Event Policy. The hospital failed to perform a root cause analysis of the event. A root cause analysis would have aided the hospital in identifying possible medical, staff, and/or equipment failures related to the care to Patient #1 and Patient #4. Had the hospital followed the Sentinel Event Policy, the analysis would have been presented to the CQI Committee, the Board of Managers, and the departments would have conducted a Failure Mode and Effects Analysis annually. These interventions would have had the potential to prevent future incidents. 8. The RN with extensive NICU experience who was primarily responsible for the care of Patient #4 after delivery, was interviewed on 6/03/09 at 2:36 PM. She stated a debriefing was held the next day for the staff involved. She stated that along with herself and the L&D RN (who stayed with the mother until the demise of the infant), the NNP was present, as well as a neonatologist from the secondary hospital, the pediatrician who responded to the call, and the obstetrician. She recalled one of the topics of the debrief was that a pediatrician could have been available sooner.	A 267		

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A 267	Continued From page 35 There was no documented evidence of this debrief. The Occurrence Report Review completed by the CO, dated 1/06/09 and amended 6/04/09, consisted of dialogue recorded during several interviews with staff that were present during the delivery. This included the Clinical Lead (an RN) at the time of event, the RN with extensive NICU experience who was primarily responsible for the care of Patient #4, the obstetrician, the L&D RN (identified in the report as an attending NICU RN), the nurse anesthetist who was responsible for the mother, and the respiratory therapist. The report also stated a second nursery RN who came on shift just after the birth of the infant, and assisted with the resuscitation effort, was interviewed on 6/04/09 via cell phone. Absent from this list of staff interviewed were the assisting physician to the obstetrician in the cesarean section and the surgical technician present during the surgery. During an interview on 6/04/09 beginning at 2:17 PM, the CO stated he was unaware of the assisting physician's role in the delivery and thought perhaps the chairman of the Board of Managers, who was assisting with the investigation, had spoken with her at some point. The Board of Managers meeting minutes were reviewed. There was no mention in the minutes to suggest they had talked to the 1st assist to the obstetrician. The CO also stated that at the time of the investigation he did not think to speak to the surgical technician. The surgical technician present during the delivery was interviewed on 6/04/09 from 10:37 AM to 10:42 AM. She stated her role during the surgery included handing the surgeon	A 267		

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A 267	Continued From page 36 instruments and assisting. She described the physician's attempts to pull the infant out by his feet but the head was "stuck." She stated she was not part of a review of processes. The Medical Executive Committee meeting minutes were reviewed. Meeting minutes dated 03/11/09 stated the (Patients last name) file was reviewed. It stated that no peer review was needed and the hospital will "trend" the obstetrician for other cases. There was no mention in the Medical Executive Committee minutes to suggest they had talked to the 1st assist to the obstetrician. The hospital's Quality Assurance failed to interview all staff involved with Patient #1 and Patient #4's case. This had the potential to result in unidentified information the staff members may have contributed which may have identified quality of care issues. 9. A nursing note, dated 12/11/09 timed at 7:38 PM, stated the NNP ordered staff to infuse sodium bicarbonate 1.2 mEq. The remainder of 6 mEq was to be infused over the next 5 minutes. However, the infusion was stopped after 1 minute. The H&P, dictated on 12/12/08 at 3:04 AM, by the NNP stated sodium bicarbonate was given, a total of 6 mEq and then a sodium bicarbonate drip was started. The infant's Medication Distribution Record stated 6 mEq sodium bicarbonate was given over 10 minutes, but was stopped after 1 minute. No further documentation was found to explain the discrepancies. The NNP was interviewed on 6/16/09 at 4:08 PM. She stated that she did order the sodium	A 267		

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A 267	Continued From page 37 bicarbonate. She stated that at some point she had realized that the sodium bicarbonate that was being used was for adults and not infants. She stated the hospital did not carry pediatric sodium bicarbonate and so it was required that the adult sodium bicarbonate was to be diluted before using. That was why she ordered the the infusion to be stopped after 1 minute. The Occurrence Report Review completed by the CO, dated 1/06/09 and amended 6/04/09, did not address the inconsistent documentation regarding the sodium bicarbonate administration. The Nursing 2008 Drug Handbook stated sodium bicarbonate is used in cardiac arrest patients. The American Academy of Pediatrics, Neonatal Resuscitation Program, Worksheet for Proposed Evidence-Based Guideline Recommendations, 2005 stated "Sodium bicarbonate is discouraged during brief CPR but may be useful during prolonged arrests after adequate ventilation is established and there is no response to other therapies" in the "absence of adequate ventilation, sodium bicarbonate administration can exacerbate intracellular hypercarbia and worsen intracellular acidosis." The secondary hospital's neonatologist's H&P, dated 12/12/08 at 7:41 AM, stated he was told there was a failure of progression of the fetus with the head stuck in the birth canal. An emergency cesarean section was done to get the child out secondary to variable decelerations. It was documented that immediately after delivery Patient #4 was noted to have no respiratory effort. He was told that intubation was performed by hospital staff at the primary hospital. He documented that no tidal CO2 detection was	A 267		

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	130065	A. BUILDING _____ B. WING _____	C 06/16/2009

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A 267	Continued From page 38 placed on the ETT. The Occurrence Report Review completed by the CO, dated 1/06/09 and amended 6/04/09, did not identify the lack of a CO2 detector. The secondary hospital's neonatologist's H&P, dated 12/12/08 at 7:41 AM, stated he was informed the patient's heart rate had dropped and oxygen saturations had not improved with intubation. He documented the baby did not have an adequate heart rate at 30 minutes of life, and the baby was noted to be limp, pale, and cyanotic with diminished pulses. The neonatologist noted that his exam revealed a pale, apneic, infant with agonal respirations. The infant had decorticate posturing with hypertonicity of the upper and lower extremities. Merriam Webster online medical dictionary defined a decorticate posture as "abnormal posturing that involved rigidity, flexion of the arms, clenched fists, and extension of the legs. The arms would be bent inward towards the body with the wrists and fingers bent and held on the chest...It was a sign of severe brain damage and requires immediate medical attention". Further, he documented the exam revealed a subgaleal hemorrhage. Patient #4's anterior frontal head was soft and flat. His pupils were equal and minimally reactive to light. The decision was made, after discussion with the infant's father, to end resuscitation efforts secondary to prolonged asphyxia. The online Merriam Webster Dictionary, 1978 edition, defined asphyxia as a "lack of oxygen or excess of carbon dioxide in the body that results in unconsciousness and often death and was usually caused by interruption of breathing or inadequate oxygen supply." The infant was subsequently transported back to the primary hospital to allow the mother to hold the baby	A 267		

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A 267	Continued From page 39 where the pediatrician later pronounced the infant's death. The hospital's Transfer of Patients from (Hospital's Name) Policy #410 dated 9/04/06, stated the hospital was to review 100% of all records of patients transferred out of the hospital to determine that the appropriate standard of care had been met. The hospital's 2008 Patient Transfer Log documented the hospital had transferred out 20 infants. The hospital's Quality Perinatal 2008 Statistics showed no documentation the transfer records were reviewed. During an interview with the hospital's CO on 6/10/09 at 9:30 AM, he stated that the hospital was "now" going to review 100% of all records of patients transferred out of the hospital. Review of Patient #4's lab results dated 12/11/08 at 8:50 PM, from the secondary hospital showed the infant's arterial blood gas results as follows: PH was 6.98 (Normal 7.33 to 7.49) PCO2 was 32 (Normal 27-40) PO2 was 37 (Normal 60-76) HCO3 was 8 (Normal 23-30) BE was -23 (Normal -3 to 3) 02 saturation 45 (Normal 92 to 100) The secondary hospital's neonatologist's H&P, dated 12/12/08 at 7:41 AM, stated his impressions included, but were not limited to, perinatal asphyxia likely immediately at delivery or shortly after, severe hypoxic ischemic encephalopathy, and severe mixed acidosis both metabolic and respiratory. The secondary hospital's neonatologist, involved in this case, was interviewed on 6/04/09 at 11:15	A 267		

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A 267	Continued From page 40 AM. He reported that he was notified of the incident and was part of the transport team as the infant was taken to and from the involved hospitals. He recalled the infant had obvious severe brain damage on physical exam, and after 15-20 minutes of continued resuscitation efforts at the secondary hospital, they discontinued aggressive treatments. The infant was left on life support measures, and the family was informed of the infants status and their options for further treatment or discontinuation thereof. The neonatologist expressed frustration at not being notified sooner, even on a consultative basis. He stated he was in his office, which was near the primary hospital, at the time of delivery and would have made himself available in any capacity that would have been helpful to save this infant. He stated that, given the status of the infant immediately after delivery, the injuries sustained most likely came from the delivery process itself. The neonatologist stated that the primary hospital had requested his partner (a neonatologist), to be involved in the review of this case. He stated he was "almost sure" the results of the autopsy were discussed as well as recommended possible policy changes to implement. The neonatologist's partner was interviewed on 6/16/09 at 3:23 PM. He stated that he did go to the hospital and debrief staff on the event. He stated that he recommended that the hospital look at the excessive use of vacuum and forceps deliveries. He also suggested that the hospital have a pediatrician in the OR for all emergent c-sections. Patient #4's autopsy report, dated 1/04/09 at 9:45 PM, documented he suffered a blunt force trauma to the head. The infant had a contusion/abrasion	A 267		

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A 267	Continued From page 41 on the right upper scalp measuring up to 2 inches. The report documented the infant had a subscapular red/blue hematoma overlying below a skull fracture of the right parietal bone. The report noted the infant had a bilateral subdural hematoma that involved the convexities at the base of the infant's brain. The report further documented there was diffuse subarachnoid hemorrhaging of the parietal and occipital lobes of the brain. The report documented there was noted blunt force trauma to the right lower leg with a blue/black contusion over the length below the knee to the ankle that was roughly circumferential. The infant's Birth Certificate Information, Physician's worksheet for Baby Data Sheet, dated 2/04/09 that was not timed, but was filled out by the NNP from the primary hospital, documented the infant sustained a "Significant birth injury skeletal fracture, peripheral nerve injury, and/or soft tissue/solid organ hemorrhage which requires intervention." The Occurrence Report Review completed by the CO, dated 1/06/09 and amended 6/04/09, documented one of the questions addressed was whether to proceed with a peer review. The chief of medicine (who was an orthopedic surgeon), deferred these decisions to the chairman of the board, who was a member of the American College of Obstetricians and Gynecologists. The CO documented the results of the 1/06/09 investigation were then discussed with the hospital's administration. In an interview on 6/03/09 at 11:05 AM, the CO stated that a peer review would only be generated as a result of a complaint from a physician or another facility.	A 267		

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A 267	Continued From page 42 During the interview on 6/04/09 at 9:00 AM, the CO stated that after his investigation was complete, the director of the Board of Managers took this information to the Medical Executive Committee. The Medical Executive Committee meeting minutes were reviewed. One meeting minutes dated 03/11/09 stated the (Patients last name) file was reviewed. It stated that no peer review was needed and the hospital will "trend" the obstetrician for other cases. He stated that a neonatologist did not do a peer review of this case. The CO was asked for the peer review policy on 6/03/09. He provided a copy of the MEDICAL STAFF BYLAWS, sections 4.6.3 through 7.2. The documents did not state when, how and who would do a peer review nor had any language about a peer review process. During the interview on 6/04/09 at 2:17 PM, the CO then stated the hospital did not have a policy that would have guided the hospital staff in the decision of obtaining an objective peer review of Patient #1's and Patient #4's case. The CFO of the hospital was interviewed on 6/04/09 from 2:03 PM to 2:15 PM. He stated peer review was not completed because it was felt the physicians involved in the case did nothing wrong. He stated that he felt the proper processes had been followed, as specified in the investigation by the CO and surgeon who assisted with the investigation. On 6/10/09 at 9:10 AM, the CO stated he had just developed a policy on peer review and this was being brought to the Medical Executive Committee meeting for approval. The hospital failed to have a policy developed for peer review. This resulted in the hospital's	A 267		

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A 267	Continued From page 43 Quality Assurances inability to review and improve the quality of physicians' patient care practices related to Patient #1 and Patient #4.	A 267		

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B 000	16.03.14 Initial Comments The following deficiencies were cited during the complaint survey of your hospital. Surveyors conducting the recertification were: Patrick Hendrickson, RN, HFS, Team Leader Aimee Hastriter, RN, HFS Teresa Hamblin, RN, MS, HFS Acronyms used in this report include: CFO - Chief Financial Officer CPR - Cardiopulmonary Resuscitation CO - Compliance Officer CO2 - Carbon Dioxide CQI - Continuous Quality Improvement ETT - Endotracheal Tube H&P - History and Physical L&D - Labor and Delivery NICU - Neonatal Intensive Care Unit NNP- Neonatal Nurse Practitioner O2 - Oxygen OR - Operating Room RN - Registered Nurse	B 000	See Attachment #1 MVH Attachment Response to Addl survey #1	7/23/09
BB115	16.03.14.200.01 Governing Body and Administration 200. GOVERNING BODY AND ADMINISTRATION. There shall be an organized governing body, or equivalent, that has ultimate authority and responsibility for the operation of the hospital. (10-14-88) 01. Bylaws. The governing body shall adopt bylaws in accordance with Idaho Code, community responsibility, and identify the purposes of the hospital and which specify at least the following: (10-14-88)	BB115	See Attachment #1 MVH Attachment Response to addl survey #1	7/23/09

Bureau of Facility Standards

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE Compliance Offic

(X6) DATE

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BB115	Continued From page 1 a. Membership of Governing Body, which consist of: (12-31-91) i. Basis of selecting members, term of office, and duties; and. (10-14-88) ii. Designation of officers, terms of office, and duties. (10-14-88) b. Meetings, (12-31-91) i. Specify frequency of meetings. (10-14-88) ii. Meet at regular intervals, and there is an attendance requirement. (10-14-88) iii. Minutes of all governing body meetings shall be maintained. (10-14-88) c. Committees, (12-31-91) i. The governing body officers shall appoint committees as appropriate for the size and scope of activities in the hospitals. (10-14-88) ii. Minutes of all committee meetings shall be maintained, and reflect all pertinent business. (10-14-88) d. Medical Staff Appointments and Reappointments; (12-31-91) i. A formal written procedure shall be established for appointment to the medical staff. (10-14-88) ii. Medical staff appointments shall include an application for privileges, signature of applicant to abide by hospital bylaws, rules, and regulations, and delineation of privileges as recommended by	BB115		

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BB115	Continued From page 2 the medical staff. The same procedure shall apply to nonphysician practitioners who are granted clinical privileges. (10-14-88) iii. The procedure for appointment and reappointment to the medical staff shall involve the administrator, medical staff, and the governing body. Reappointments shall be made at least biannually. (10-14-88) iv. The governing body bylaws shall approve medical staff authority to evaluate the professional competence of applicants, appointments and reappointments, curtailment of privileges, and delineation of privileges. (10-14-88) v. Applicants for appointment, reappointment or applicants denied to the medical staff privileges shall be notified in writing. (10-14-88) vi. There shall be a formal appeal and hearing mechanism adopted by the governing body for medical staff applicants who are denied privileges, or whose privileges are reduced. (10-14-88) e. The bylaws shall provide a mechanism for adoption, and approval of the organization bylaws, rules and regulations of the medical staff. (10-14-88) f. The bylaws shall specify an appropriate and regular means of communication with the medical staff. (10-14-88) g. The bylaws shall specify departments to be established through the medical staff, if appropriate. (10-14-88)	BB115		

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BB115	Continued From page 3 h. The bylaws shall specify that every patient be under the care of a physician licensed by the Idaho State Board of Medicine. (10-14-88) i. The bylaws shall specify that a physician be on duty or on call at all times. (10-14-88) j. The bylaws shall specify to whom responsibility for operations, maintenance, and hospital practices can be delegated and how accountability is established. (10-14-88) k. The governing body shall appoint a chief executive officer or administrator, and shall designate in writing who will be responsible for the operation of the hospital in the absence of the administrator. (10-14-88) l. Bylaws shall be dated and signed by the current governing body. (10-14-88) m. Patients being treated by nonphysician practitioners shall be under the general care of a physician. (10-14-88) This Rule is not met as evidenced by: Based on interviews and review of Quality Assurance and Performance Improvement documents, Medical Staff Bylaws, Medical Executive Committee meeting minutes, Board of Managers meeting minutes, patient records and hospital policies, it was determined the governing body failed to ensure that the medical staff were accountable to the governing body for the quality of care provided to patients. Further, it was determined the governing body failed to ensure the hospital maintained an effective quality	BB115		

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BB115	Continued From page 4 assessment and performance improvement program. This resulted in a missed opportunity for systematic reviews to improve patient care and outcomes. 1. Refer to A0049 Standard Citation for medical staff accountability and the failure of the governing body to develop and implement a written process for the overall review of the quality of physicians' practices, such as peer review. 2. Refer to A263 Condition of Participation as it relates to the failure of the hospital to ensure the Quality Assurance and Performance Improvement program analyzed all quality indicators in order to assess processes of patient care and the hospital's code blue responses.	BB115		
BB124	16.03.14.200.10 Quality Assurance 10. Quality Assurance. Through administration and medical staff, the governing body shall ensure that there is an effective, hospital-wide quality assurance program to evaluate the provision of care. The hospital must take and document appropriate remedial action to address deficiencies found through the program. The hospital must document the outcome of the remedial action. (10-14-88) This Rule is not met as evidenced by: Based on interviews and review of Quality Assurance and Performance documents, Medical Staff Bylaws, Medical Executive Committee meeting minutes, Board of Managers meeting minutes, patient records and hospital policies, it was determined the hospital failed to maintain an effective quality assessment and performance improvement program. This resulted in a missed	BB124	See Mock Attachment # 1 Response to Survey	7/23/09

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BB124	Continued From page 5 opportunity for systematic reviews to improve patient care and outcomes. The findings include: 1. Refer to A267 as it relates to the failure of the hospital to ensure its Quality Assurance and Performance Improvement program analyzed all quality indicators in order to assess processes of patient care and hospital services.	BB124		

IDAHO DEPARTMENT OF
HEALTH & WELFARE

C. L. "BUTCH" OTTER – Governor
RICHARD M. ARMSTRONG – Director

DEBRA RANSOM, R.N.,R.H.I.T., Chief
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July 14, 2009

Jeff Sayer
Mountain View Hospital
2325 Coronado Street
Idaho Falls, ID 83404-1389

Provider #130065

Dear Mr. Sayer:

On **June 16, 2009**, a complaint survey was conducted at Mountain View Hospital. The complaint allegations, findings, and conclusions are as follows:

Complaint #ID00004019

Allegation: Babies that were delivered by forceps, by a specific physician, suffered injuries.

Findings: An unannounced visit was made to the hospital on June 3, 2009. Seventeen medical records were reviewed, including those of three babies delivered by forceps, 8 babies transferred out of the hospital for continued care, 2 babies cared for in the hospital, and 4 mothers. Quality Assurance and Performance Improvement documents, Medical Staff Bylaws, Medical Executive Committee meeting minutes, Board of Managers meeting minutes, and hospital policies were reviewed. Staff were interviewed.

The hospital's Quality Assurance and Performance Improvement documents for 2008, documented 3 babies were delivered by forceps, all by the same physician. No evidence was found that any of these infants had suffered injury.

However, one infant whose delivery included the use of suction, did sustain fatal injury. The infant was ultimately delivered via caesarean section. The infant's head was tightly wedged in the mother's pelvic area. The infant was pulled from the mother by the infant's feet.

As a result of the complications experienced during delivery, the infant suffered a blunt force trauma to the head. The trauma included a contusion/abrasion, multiple hematomas, a skull fracture, diffuse subarachnoid hemorrhaging of the parietal and occipital lobes of the brain related to a traumatic birth.

During the course of the investigation, it was determined the governing body failed to have written policies and procedures developed and implemented for overall review of the quality of physicians' practices.

The hospital did not identify the difficult delivery and subsequent infant's death as a Sentinel Event, even though it met the hospital's definition of a Sentinel Event. Therefore, a root cause analysis of the event was not completed. It was determined the hospital's Quality Assurance and Performance Improvement Program did not analyzed all quality indicators and patient adverse events to assess patient care and services.

Although it was not substantiated that babies, that were delivered by forceps, suffered injuries, it was identified that one infant, whose delivery included the use of suction, did sustain a fatal injury. An unrelated deficiency was cited at 42 CFR 482.12: Condition of Participation for Governing Body and 42 CFR 482.21: Condition of Participation for Quality Assessment and Performance Improvement, for the failure of the hospital to identify the difficult delivery and subsequent infant's death as a Sentinel Event, even though it met the hospital's definition of a Sentinel Event.

Conclusion: Unsubstantiated. Lack of sufficient evidence.

As none of the complaints were substantiated, no response is necessary. Thank you for the courtesies and assistance extended to us during our visit.

Sincerely,

PATRICK HENDRICKSON
Health Facility Surveyor
Non-Long Term Care

SYLVIA CRESWELL
Co-Supervisor
Non-Long Term Care

PH/mlw